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SPECIAL ISSUE

Risk assessment of biological hazards for consumer protection

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ABSTRACT

EFSA´s scientific Panel on Biological Hazards (BIOHAZ Panel) provides independent scientific advice on biological hazards in relation to food safety and food-borne diseases. This covers food-borne zoonoses, food microbiology, food hygiene, antimicrobial resistance (AMR), transmissible spongiform encephalopathies (BSE/TSEs) and associated waste management issues. Most of the activities of the BIOHAZ Panel focus on human health and the whole food chain and on science-based interventions to lower the risk to consumers. In the future, food-borne disease burden estimations are foreseen to become increasingly relevant. The risk assessments done by the BIOHAZ Panel are in line with the EU (European Union) strategy of one health, include a farm to fork approach and in many cases have a high multidisciplinary component. Whenever possible, the Panel applies this risk assessment framework developed by Codex Alimentarius as a basis for their work on food safety. The outcomes of some of the activities during the last three to four years are presented. From these examples of recent BIOHAZ opinions it can be seen that the work covers different approaches, ranging from quantitative risk assessments over structured qualitative risk assessment/risk ranking to opinions with short deadlines summarising existence knowledge from scientific literature. The approach taken depends on both the terms of reference (ToR) as received from the EC (European Commission), the available data and resources, and last but not least the time frame for the work following the risk managers' needs.

KEY WORDS

Pathogens, zoonoses, food, meat, BSE/TSE, risk assessment

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INTRODUCTION

Food safety needs to be controlled in an integrated longitudinally farm to fork approach. In the 1980's the main focus was on using good hygiene practices, in the 90's the HACCP (Hazard Analysis Critical Control Point) concept was implemented, and in the 2000's the Risk analysis framework developed by the Codex Alimentarius Commission (CAC) in the 90's has started being implemented at the EU level.

In the European Union, both EC and EFSA use this risk analysis framework as basis for their work on food safety. EFSA´s scientific Panel on Biological Hazards (BIOHAZ Panel) provides independent scientific advice on biological hazards in relation to food safety and food-borne diseases. This covers food-borne zoonoses, food microbiology, food hygiene, antimicrobial resistance (AMR), transmissible spongiform encephalopathies (BSE/TSEs) and associated waste management issues. Most of the activities of the BIOHAZ Panel focus on human health and the whole food chain and on science-based interventions to lower the risk to consumers. In the future, food-borne disease burden estimations are foreseen to become increasingly relevant.

The BIOHAZ Panel addresses mandates related to general risk assessments (qualitative and quantitative) of food-borne pathogens in different animal population and food commodities. Providing scientific advice on food hygiene and food-borne zoonoses including antimicrobial resistance issues constitutes one of the main areas of work, and during the latest mandate of the Panel (2009-2012), 33 opinions on these subjects have been adopted.

The BIOHAZ Panel also assesses applications related to alternative treatments for disposal of different categories of Animal By-Products (ABP), TSE diagnostic tests and on the efficacy and possible development of AMR of treatments for the decontamination of food of animal origin. In this area, the Panel in the above period has produced 21 assessments plus 3 opinions on guidance for applicants. Moreover, an annual task of the BIOHAZ Panel is to produce a list of microorganisms that have a Qualified Presumption of Safety (QPS) as an EFSA tool for simplifying risk assessments concerning the safety of microorganisms, mostly in the area of feed additives by the Panel on Additives and Products or Substances used in Animal Feed (FEEDAP Panel).

In the area of TSEs, the BIOHAZ Panel has played a key role in providing scientific advice to risk managers allowing the adaptation of the EU regulations following the evolution of the epidemiological situation and according to the EU TSE Road Maps 2005 and 2010. In the period from March 2009 to June 2012, 20 Scientific Opinions, 3 Technical Reports and one Statement on TSEs have been adopted.

It is important to highlight that the risk assessments done by the BIOHAZ Panel in line with the EU strategy of one health[3] include a farm to fork approach, and in many cases they have a high multidisciplinary component. As a consequence, the BIOHAZ Panel works in some cases in close collaboration with sister agencies in the EU public health area such as the European Medicines Agency (EMA) and the European Centre for Disease Control (ECDC), the EC non-food Scientific Committees (SCHER and SCENIHR) and last but not least with other EFSA Scientific Panels such as the Panel on Animal Health and Welfare (AHAW), the Panel on Contaminants (CONTAM), the Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF) and the Genetically Modified Organisms (GMO) Panel.

In this paper we briefly describe the outcome of some of our activities during the period 2009-2012.

[3] Available from http://ec.europa.eu/food/dyna/conference/

1. QUANTITATIVE MICROBIOLOGICAL RISK ASSESSMENT OF FOOD-BORNE ZOONOSES

Quantitative Microbiological Risk Assessment (QMRA) of food-borne pathogens at European level has proven a useful tool to enable risk managers to evaluate the feasibility and the cost-benefit ratio of introducing control measures and targets to further protect the public health of European consumers. QMRAs have been used by the BIOHAZ Panel to support Scientific Opinions and to better reply to the questions asked by the risk managers to further protect consumers from food risks. Examples are: Quantitative estimation of the impact of setting a new target for the reduction of *Salmonella* in breeding hens of *Gallus gallus* (EFSA, 2009a), *Salmonella* in slaughter and breeding pigs (EFSA Panel on Biological Hazards (BIOHAZ), 2010b), *Salmonella* in laying hens and broilers (EFSA Panel on Biological Hazards (BIOHAZ), 2010a, 2011a), and *Campylobacter* in broilers (EFSA Panel on Biological Hazards (BIOHAZ), 2011b).

In 2011, a QMRA model was developed and used in the framework of the Scientific Opinion on a QMRA of *Campylobacter* in broiler meat to determine the effect of interventions from farm to fork on the incidence of human campylobacteriosis. Reductions to the public health risk of campylobacteriosis could be achieved through a variety of interventions, both in primary production or at the slaughterhouse, with different impacts. Reductions of public health risk using targets at primary production or microbiological criteria were also estimated through modelling using additional models.

In the opinion several different control options were assessed in relation to their efficacy of reducing the public health risk from *Campylobacter* in broiler meat. Thus it was estimated that there are approximately nine million cases of human campylobacteriosis per year in the EU27. The disease burden of campylobacteriosis and its sequelae is 0.35 million disability-adjusted life years (DALYs) per year and the total annual costs are 2.4 billion Euros. Broiler meat may account for 20 % to 30 % of these, while 50 % to 80 % may be attributed to the chicken reservoir as a whole (broilers as well as laying hens). The public health benefits of controlling *Campylobacter* in primary broiler production are expected to be greater than control later in the chain as the bacteria may also spread from farms to humans by other pathways than broiler meat.

Strict implementation of biosecurity in primary production and GMP/HACCP during slaughter may reduce colonisation of broilers with *Campylobacter*, and contamination of carcasses. After slaughter, a 100 % risk reduction can be reached by irradiation or cooking of broiler meat on an industrial scale. More than 90 % risk reduction can be obtained by freezing carcasses for 2-3 weeks. A 50-90 % risk reduction can be achieved by freezing for 2-3 days, hot water or chemical carcass decontamination. Achieving a target of 25 % or 5 % between flock prevalence (BFP) in all Member States (and assuming that those with lower BFP keep this) is estimated to result in 50 % and 90 % reduction of public health risk, respectively. A public health risk reduction > 50 % or > 90 % could be achieved if all batches would comply with a microbiological criteria with a critical limit of 1 000 or 500 CFU (colony forming units)/gram of neck and breast skin, respectively, while 15 % and 45 % of all tested batches would not comply with these criteria.

The risk assessment has provided valuable information to the EC and enables the risk managers to make decisions on the most cost-effective risk management options.

2. ANTIMICROBIAL RESISTANCE

The BIOHAZ Panel has addressed several issues related to antimicrobial resistance like assessment of the public health significance of methicillin resistant *Staphyloccus aureus* (MRSA) in animals and foods (EFSA, 2009b), Joint opinion on antimicrobial resistance (AMR) focused on zoonotic infections (EFSA Panel on Biological Hazards (BIOHAZ), 2009), and more recently a scientific opinion on the public health risks of bacterial strains producing extended-spectrum β-lactamases (ESBL) and/or AmpC β-lactamases in food and food-producing animals (EFSA Panel on Biological Hazards (BIOHAZ), 2011d). In this latter opinion it is concluded that there are no data on the comparative efficiency of individual control options in reducing public health risks caused by ESBL and/or AmpC-producing bacteria related to food-producing animals. Prioritisation is complex, but it is considered

that a highly effective control option would be to stop all uses of cephalosporins/systemically active 3rd/4th generation cephalosporins, or to restrict their use (use only allowed under specific circumstances). As co-resistance is an important issue, it is also of high priority to decrease the total antimicrobial use in animal production in the EU.

3. GUIDANCE DOCUMENTS AND EFFICACY EVALUATION

Article 3(2) of Regulation (EC) No 853/2004 of the European Parliament and Council[4], which lays down specific hygiene rules for food of animal origin, constitutes the legal basis for the use of substances other than potable water or clean water to remove surface contamination from foods of animal origin intended for human consumption. The use of such substances can only be considered if their toxicological safety and efficacy can be demonstrated. Therefore a joint AFC (EFSA Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food)/BIOHAZ draft guidance document for the submission of data for the evaluation of the safety and the efficacy of substances intended to be used to remove microbial surface contamination of food of animal origin, was developed (EFSA, 2006). In 2010 the BIOHAZ Panel of EFSA revised the joint AFC/BIOHAZ guidance document (EFSA Panel on Biological Hazards (BIOHAZ), 2010c). This guidance requires data and information about the safety and efficacy of the substances, as well as examples of study designs at the laboratory and at the slaughterhouse in order to demonstrate these attributes. It also includes the factors that should be considered when monitoring the safety and efficacy of a substance that has already been authorised and used.

In addition, all the factors related to the potential occurrence of acquired reduced susceptibility to biocides and/or resistance to therapeutic antimicrobials and the issues related to the environmental risk due to the use of such substances are considered in this guidance. The evaluation of these aspects is divided into pre-market and post-market evaluation. These guidance documents showed very useful in the evaluation and efficacy of several decontaminating agents i.e. lactic acid for the removal of microbial surface contamination of beef carcasses, cuts and trimmings (EFSA Panel on Biological Hazards (BIOHAZ), 2011e), LISTEX P 100 for fish (EFSA Panel on Biological Hazards (BIOHAZ), 2012c) and Cecure® for Poultry (EFSA Panel on Biological Hazards (BIOHAZ), 2012d)

4. RISK BASED MEAT INSPECTION

The BIOHAZ Panel has finalised opinions dealing with meat inspection of swine (EFSA Panel on Biological Hazards (BIOHAZ), 2011c) and poultry (EFSA Panel on Biological Hazards (BIOHAZ), 2012e). The terms of reference for this work was provided by the EC and was, summarised, to identify and rank the main risks for public health that should be addressed by meat inspection at EU level, to assess the strengths and weaknesses of the current meat inspection, and to recommend new inspection and other methods fit for the purpose of meeting the overall objectives of meat inspection.

The public health related strengths of **ante-mortem inspection** include inspection of individual animals, animal identification, evaluation of animal cleanliness and use of food chain information (FCI). However, in current practice, the latter is actually utilised in relation to public health only to a limited degree. Since pigs carrying currently most relevant zoonotic agents do not or only very seldom show clinical symptoms, the strengths of ante-mortem inspection are mainly related to animal welfare and animal health. FCI is insufficiently utilised mainly due to the lack of adequate and harmonized indicators that could help risk-classifying the pigs in a public health aspect. Furthermore, the very large numbers on animals arriving for slaughter - which are all healthy at first observation - do not contribute to opportunities and motivation for proper clinical examination.

The strengths of **post-mortem inspection** are mainly related to animal welfare and animal health aspects. Classical zoonotic diseases, such as tuberculosis, trichinellosis, and brucellosis, which can be detected by post-mortem examination of pigs, have become controlled in many areas where modern systems of animal husbandry, disease control and animal health care were introduced. Hence, the

[4] Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for on the hygiene of foodstuffs. OJ L 139, 30.4.2004, p. 55–205.

ability of current post-mortem meat-inspection to detect lesions caused by e.g. mycobacteria or *Taenia solium cysticercus* (macroscopically) or *Trichinella* spp. (by specific laboratory methods) is only relevant in regions where they are present.

Currently relevant potential threats to public health associated with slaughtered pigs including agents like *Salmonella, Y. enterocolitica* and *Toxoplasma* are carried by animals without symptoms, but current meat inspection was not designed to detect and/or eliminate these agents. Bacterial species isolated from pathological/anatomical abnormalities detected at current post-mortem inspection of pigs does not impose a serious health threat to consumers. Nevertheless, finding abscesses is the reason to declare the affected meat unfit for human consumption as a meat quality issue and aesthetically unacceptable.

Based on qualitative risk assessment of human pathogenic microorganisms from pig carcasses within the EU, *Salmonella* spp. is considered of high relevance and *Yersinia enterocolitica*, *Toxoplasma gondii* and *Trichinella* spp. as of medium relevance. Other hazards are considered of low relevance. Because current meat inspection of pigs does not target, and is not able to protect the consumer against the most important "new hazards" (*Salmonella, Y. enterocolitica, Toxoplasma),* appropriate procedures for these hazards have to be developed anew. Whilst the current meat inspection targets *Trichinella,* the approach used can be further developed so to be more dynamic and flexible. The above ranking relates to the EU as a whole and refinements reflecting differences between regions or production systems may be necessary if/where hazard monitoring data indicate. Furthermore, as new hazard(s) might emerge and/or hazards that presently are not a priority might become more relevant over time or in some regions, the risk ranking is to be revisited regularly. To provide a better evidence base for future rankings, studies should be carried out to systematically collect data for source attribution and to identify emerging pork-borne hazards, including the collection of more systematic data for ranking.

For poultry meat inspection *Campylobacter* spp. and *Salmonella* spp. are considered of high public health relevance. Extended-spectrum and AmpC Beta-Lactamase (ESBL/AmpC) gene carrying bacteria were considered to be of high to medium (*E. coli*) and medium (*Salmonella*) public health relevance.

Effective control of the main hazards in pigs and poultry in the context of meat inspection is possible only through a comprehensive pork carcass safety assurance program combining a range of preventative measures and controls applied both on-farm and at-abattoir in a longitudinally integrated way. A prerequisite for an effective pork carcass safety assurance system is setting of **measurable targets** in respect to the main hazards to be achieved on final, chilled carcasses. These would also indicate what has to be achieved at earlier steps in the food chain and focus related control measures.

On the basis of these opinions the risk managers have now started to draft a new legal framework for a modern risk based meat inspection.

5. BSE/TSE RELATED RISKS

The favourable evolution both of the bovine spongiform encephalopathy (BSE) and UK variant Creutzfeldt-Jakob disease (vCJD) epidemics in recent years – to be well considered as the success story of the European response to BSE (Budka, 2011) – changed the scope of TSE-related risk questions to EFSA, from more basic risk assessments to evaluation of potential relaxation of costly BSE control measures as depicted in the EU TSE Roadmaps. Moreover, recognition of the wide diversity of prion strains in the field, including three new forms of animal TSEs (L-type Atypical BSE, H-type Atypical BSE and Atypical scrapie), has complicated disease diagnosis and surveillance, as well as scientific assessment of the overall TSE risks to humans.

EFSA and the ECDC delivered a joint scientific opinion on any possible epidemiological or molecular association between TSEs in animals and humans (EFSA Panel on Biological Hazards (BIOHAZ) and

ECDC, 2011). That opinion confirmed Classical BSE prions as the only TSE agents demonstrated to be zoonotic so far, but the possibility that a small proportion of human cases so far classified as "sporadic" CJD might be of zoonotic origin could not be excluded. Moreover, transmission experiments to non-human primates suggest that some TSE agents in addition to Classical BSE prions in cattle [namely L-type Atypical BSE, Classical BSE in sheep, transmissible mink encephalopathy (TME) and chronic wasting disease (CWD) agents] might have zoonotic potential. In particular the L-type Atypical BSE agent might be similar or even more virulent to humans than the Classical BSE agent. While mankind has been in contact with small ruminants for millennia, there is no epidemiological evidence to suggest that classical scrapie is zoonotic; however, experimental transmission data on humanised mice and non-human primates have been very scarce so far.

Another major field was assessment of the EU-wide tailing of the BSE epidemic as juxtaposed with the adequacy of present surveillance measures and a potential revision of the BSE monitoring programme. The BIOHAZ Panel confirmed that the BSE epidemic has been declining and is converging to the sensitivity limit of a surveillance system that uses currently approved rapid BSE tests. It became clear, however, that the stage of the epidemic differed between groups of EU Member States. Thus, the country- or group-wise development of the epidemic was assessed by two models that provided an estimate of the number of BSE cases that would be missed in Member States under several scenarios, including an increase in the current age for BSE testing in the healthy slaughtered and at risk cattle testing groups. For some Member States, the BIOHAZ Panel recommended that in order to monitor the trend of the Classical BSE epidemic and the trend in the age of the cases observed, the results of future testing years should be evaluated. Moreover, it recommended to comprehensively reassess the sensitivity of the present or intended new EU surveillance system for detecting the prevalence of Atypical BSE, re-emergence of Classical BSE, or the emergence of a novel TSE in cattle.

With regard to present risk mitigation measures, BSE/TSE infectivity was assessed in small ruminant tissues. The reduction of the infectivity associated to the carcass of an infected individual achieved by the current SRM policy in small ruminants for Classical and Atypical scrapie and BSE was estimated. For Classical scrapie, it was concluded that the current specified risk material (SRM) policy allows a reduction of the relative infectivity associated to the carcass of an infected animal of about 1 $\log_{10}$. When considering BSE in small ruminants, the data available argued against any current widespread BSE epidemic within the EU small ruminant population. Because of lack of data, the Panel was not in a position to provide an assessment of the current atypical scrapie infectious load entering into the food chain.

Another important area for BIOHAZ risk assessments is treatment of animal waste and by-products. With regard to BSE/TSE-related risks, opinions were given on topics as diverse as composting on-farm of dead poultry; on-site treatment of pig carcasses; isolation in proofed pit on-farm of dead poultry; oleochemical processes to minimise TSE risks in Cat. 1 ABP; and revision of the quantitative risk assessment (QRA) of the BSE risk posed by processed animal proteins (PAPs).

CONCLUSIONS

From the above examples of recent BIOHAZ opinions it can be seen that the work covers different approaches ranging from quantitative risk assessments over structured qualitative risk assessment/risk ranking to opinions with short deadlines summarising existence knowledge from scientific literature. The approach taken depends on both the ToR as received from the EC, the available data and resources and last but not least the timeframe for the work.

The BIOHAZ Panel has just published two opinions (self-tasking) on experiences and lessons learnt from modelling and risk ranking of biological hazards (EFSA Panel on Biological Hazards (BIOHAZ), 2012a,b).

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